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REMARKS

Applicant would like to thank the Examiner Samuel P. Siefke for his consideration given to the above-identified application and appreciates his courtesy extended during a personal interview with Applicant's representatives, Jeffrey A. Lindeman, Gabriele Leißeler-Gerstl and Cecilia Lopez-Chua, on September 11, 2006.

During the interview, Examiner Siefke and Applicant's representatives discussed the claimed invention and prior art. Examiner Siefke reviewed the prosecution file history to generally understand the basis of the rejections issued by previous Examiner Latoya Cross and the indicated allowable subject matter. However, on the Interview Summary, there was "no agreement with respect to claims being in condition for allowance." Nevertheless, Applicant intends to respond to the Office Action dated May 18, 2006, with appropriate arguments and amendments. One concerning issue raised by Examiner Siefke was the Applicant's use of the term "content" in claim 1, at line 5. According to Examiner Siefke, such term is vague and needs clarification.

Claims 13-18 and 23 are pending for consideration, of which claim 13 is independent. Claims 1-12, 19-22 and 24-26 are cancelled. Applicant has revised claim 1 by (1) incorporating a recited element of claim 17 into the claim; (2) inserting the phrase "containing a liquid" after the term "cartridge" at line 2; and (3) substituting the phrase "with a content of the cartridge" with the phrase "with the liquid within the cartridge" at line 5.

In claim 17, the phrase "two half-tubes are connected by a joint and wherein the" has been deleted from the claim.

Pending claims 13-18 (along with claims 19-21) were introduced and based on originally-filed and canceled claims 4-6 and 9, which were found allowable by former Examiner Patricia K. Bex but were rejected under section 112, second paragraph (see Office Action mailed December 11, 2001). In a response/amendment dated January 26, 2003, Applicant introduced claim 23, which was also found allowable. In fact, throughout the entire prosecution period ranging from December 11, 2001 to June 13, 2005, both Examiners Bex and Cross had allowed the subject matter of claims 13-18 and 23 and these claims were never rejected based on any prior art cited in any of the Office Actions issued prior to May

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18, 2006. However, it was only until the issuance of the current Office Action mailed May 18, 2006, wherein Examiner Cross rejected these claims under section 103(a).

Referring now to the current Office Action, claims 13-18 and 23 were rejected under 35 U.S.C. §103(a), as being obvious over U.S. Patent 4,534,939 to Smith *et al.* (hereinafter "Smith"). Applicant respectfully traverses this rejection.

Smith teaches an improved gas flow cartridge that utilizes a syringe needle to fill a quantity of fluid sample into the reaction chamber for analytical testing. Smith, however, fails to teach or suggest a sample-taking means that includes two half-tubes connected to each other by a joint, as presently claimed for the reasons provided hereinbelow.

Independent claim 13, as amended, now includes the recited element of claim 17, *i.e.*, the sample-taking means comprising two half-tubes connected to each other by a joint to form a sample chamber, and optionally a surplus chamber. Specification, pp. 3-4 and Figure 2. In addition, the sample-taking means is removable from the housing for the user to collect the test sample. Regardless whether an elastic web joint or a film hinge is used, the two-half tubes can open apart to form a "V." A sample substance can be collected by pressing the half tubes back together to close in a form-fit to form a complete tube, also known as the sample chamber. The sample substance, in exactly defined amount, is contained in the sample chamber, optionally with surplus material contained in the rear part of the sample-taking means, *i.e.*, surplus chamber. Specification, pp. 6-7 and Figure 2. The claimed device containing the sample-taking means provides safe handling of sample material that can be toxic or caustic. Specification, pp. 9 and Figure 2.

As stated in the Office Action mailed December 11, 2001, the reasons for the indication of allowable subject matter are as follows:

"The instant claims (original claims 4-6 and 9) are drawn to a device for taking and examining samples. While numerous specimen test unit exist comprising a housing containing a sample-taking means, cartridge, and testing elements, none of the prior art teach the sample taking means consisting of two-half tubes which are connected with each other by a joint or elastic web." (Office Action mailed 12/11/01, pp. 7-8).

In addition, Examiner Cross herself acknowledged that "Smith differ[s]" from the

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claimed invention in that "there is no disclosure of the sample-taking means being comprised of two half tubes that are connected to each other." Office Action mailed May 18, 2006, page 3, lines 3-4. However, in rejecting claims 13-18 and 23 under section 103(a) over Smith, Examiner Cross cited *In re Dulberg* to state that "it would be obvious to make a structure separable if it were considered desirable for any reason to obtain access into the structure." The Examiner took the position that "by making the sample-taking means a two-part component is insufficient to make the claims patentable" because "one of the ordinary skill in the art would have recognized that gaining access to the inside of the sample-taking means would be advantageous if only for the reason of removing sample from or putting sample into the sample-taking means manually."

Applicant respectfully disagrees with the Examiner's position and consider her application of *In re Dulberg* to reject the claimed invention as improper. This is because the two-half tubes that comprise the sample-taking means are connected to each other and are, therefore, not removable nor separable for one of the ordinary skill in the art to gain access to the inside of the sample-taking means.

Based on the above reasons and amendments presented above, Applicant respectfully submits that Smith fails to disclose or suggest the device for taking and examining samples as presently claimed herein. In addition, the Examiner has failed to establish a *prima facie* case of obviousness.

As mentioned above, the subject matter of claims 13-18 and 25 has always been allowed and was never rejected based on any of the prior art cited, including the Smith reference, by any of the Examiners. However, to expedite allowance of the application, Applicant has amended independent claim 13 by incorporating a recited element of claim 17. To address Examiner Siefke's concern over the use of the term "content," Applicant has amended claim 13 by introducing the phrase "containing a liquid" after the term "cartridge" at line 2; and replacing the phrase "with a content of the cartridge" with the phrase "with the liquid within the cartridge" at line 5. Applicant respectfully submits that the above-mentioned amendments to the claims are supported by the entire specification, particularly at pages 2-3 and 7-8 and no new matter has been introduced. Accordingly, Applicant earnestly requests that the Examiner enter these amendments and reconsider and withdraw her rejection

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of claims 13-18 and 23 under 35 U.S.C. § 103(a).

Claims 13-18 and 23 were also rejected under the same condition as the Smith reference, as being obvious over U.S. Patent 6,048,735 to Hessel *et al.* (hereinafter "Hessel"), in view of U.S. Patent 5,096,699 to Lauks *et al.* (hereinafter "Lauks"). Applicant respectfully traverses this rejection.

Hessel teaches a delivery device that uses a syringe to deliver various fluids stored from individual compartments into a sensor laminate for the detection of target molecules in biological fluids. In addition, Lauks teaches a system that comprises a disposable sensing device and a reader where a fluid sample is drawn via capillary action into the orifice of the second conduit for mixing with the reagents and then be used for measurement or detection. Similar to the Smith reference, both Hessel and Lauks, either individually or in combination fail to teach or suggest the claimed device that comprises a sample-testing means that comprises two half-tubes connected to each other by a joint.

Accordingly, the Examiner has failed to establish any motivation to combine the teachings of Hessel and Lauks. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple references. *See In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). *See also* MPEP §2143.01 (The prior art must suggest the desirability of the claimed invention). A statement that combination of the prior art to meet the claimed invention would have been within the ordinary skill in the art is not alone sufficient to establish a *prima facie* case of obviousness. *See* MPEP §2143.01.

Based on the foregoing amendments and remarks set forth above, Applicant respectfully submits that Hessel, in view of Lauks, also fails to disclose or suggest the claimed device for taking and examining samples. In addition, the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, Applicant earnestly requests that the Examiner reconsider and withdraw the above-mentioned §103(a) rejection.

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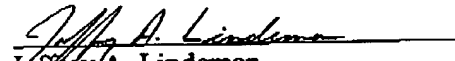
CONCLUSION

For at least the reasons set forth above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. A fee for extension of time for three (3) months is due for filing this response. The Commissioner is hereby authorized to charge any payment deficiency to Deposit Account No. 19-2380 referring to Docket No. 032034-004000.

Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

Respectfully submitted,

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